

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

BROMBERG & SUNSTEIN LLP
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UNITED STATES OF AMERICA

DOCKETED

INVITATION TO PAY ADDITIONAL FEES

(PCT Article 17(3)(a) and Rule 40.1)

Applicant's or agent's file reference
1581/140 WO

International application No.
PCT/US2004/005602

Applicant

LAVIPHARM S.A.

Date of mailing
(day/month/year)

12/08/2004

PAYMENT DUE

within 45 ~~days~~ days
from the above date of mailing

International filing date
(day/month/year)

26/02/2004

1. This International Searching Authority

- (i) considers that there are 4 (number of) inventions claimed in the international application covered by the claims indicated ~~below~~ on the extra sheet:

and it considers that the international application does not comply with the requirements of unity of invention (Rules 13.1, 13.2 and 13.3) for the reasons indicated ~~below~~ on the extra sheet:

- (ii) ☒ has carried out a partial international search (see Annex) ☐ will establish the international search report on those parts of the international application which relate to the invention first mentioned in claims Nos.:

1-36, 38-69

- (iii) will establish the international search report on the other parts of the international application only if, and to the extent to which, additional fees are paid

2. The applicant is hereby **invited**, within the time limit indicated above, to pay the amount indicated below:

EUR 1.550,00 x 3 = EUR 4.650,00
Fee per additional invention number of additional inventions total amount of additional fees

Or, _____ x _____ = _____

The applicant is informed that, according to Rule 40.2(c), **the payment of any additional fee may be made under protest**, i.e., a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fee is excessive.

3. ☐ Claim(s) Nos. _____ have been found to be unsearchable under Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention.

Name and mailing address of the International Searching Authority



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EINSCHREIBEN

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-36,38-69

The first invention is directed to a method of making an active layer comprising a polymer and a volatile substance, the active layer being formed on a release liner; and to devices and patches comprising the active polymer layer on the release liner.

2. claim: 37

The second invention is directed to a method of making an active layer comprising a polymer and a volatile substance, the active layer being formed on a side of a breathable layer which controls the rate of delivery of the volatile substance, the opposite side of the breathable layer being covered at least in part by a release liner.

3. claims: 70-74

The third invention is directed to a patch comprising multiple release liners for delivering a volatile substance at a controlled rate, the patch comprising an active layer having a volatile substance, at least two release liner segments covering one side of the active layer and a barrier layer disposed on an opposite side of the active layer from the at least two release liner segments.

4. claims: 75-81

The fourth invention is directed to a reduced adhesion patch for delivering a volatile substance, the patch comprising an active layer having a volatile substance, a barrier layer attached to the active layer and a fractional adhesion layer adjacent to an apposite side of the barrier layer from the active layer.

In fact, the common concept linking the above mentioned inventions is the provision of products comprising an active layer for the delivery of volatile substances to the environment and methods of making such products comprising an active layer.

However, this common concept is not novel in view of the state of the art cited in the International Search Report (see for example documents WO-A-98 17 263, examples 1-2 or WO-A-01 52 823, examples 1-9).

Therefore, the above mentioned inventions do not have any "special technical feature" in common that defines a contribution which each of

the inventions, considered as a whole, makes over the prior art (Rule 13.2 PCT).

Consequently, these inventions are not so linked as to form a single general inventive concept as required by Rule 13.1 PCT.

Annex Form PCT/ISA/206
COMMUNICATION RELATING TO THE RESULTS
OF THE PARTIAL INTERNATIONAL SEARCH

I. International Application No
PCT/US2004/005602

1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relate to the invention first mentioned in claims Nos.:
2. This communication is not the international search report which will be established according to Article 18 and Rule 43. see 'Invitation to pay additional fees'
3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.
4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98/17263 A (COPLEY PHARMACEUTICAL INC) 30 April 1998 (1998-04-30)	1-4, 19-30, 32-34, 38-53, 56-59, 68,69
Y	page 3, line 7 - page 13, line 27; figure 1; examples 1,2	5-18, 60-67
X	WO 01/52823 A (KANIOS DAVID ; NOVEN PHARMA (US)) 26 July 2001 (2001-07-26)	1-4, 19-30, 32-35, 38-54, 56-58, 68,69
Y	page 8, line 10 - page 30, line 17; figure 1; examples 1-9	36,55

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 97/04758 A (CAL INT LTD ; BYRNE WILLIAM (IE); MCCAFFERTY DERMOT (IE)) 13 February 1997 (1997-02-13)</p> <p>page 2, line 10 - page 6, line 33; figure 1; example 1</p>	<p>1-4,19, 22, 26-30, 32,38, 39,42, 46-51, 56-58, 68,69</p>
Y	<p>WO 02/067677 A (LAVIPHARM SA) 6 September 2002 (2002-09-06)</p> <p>page 7, line 4 - page 9, line 30; examples 1-3</p>	<p>5,6, 8-18, 60-67</p>
Y	<p>WO 95/16754 A (MINNESOTA MINING & MFG) 22 June 1995 (1995-06-22)</p> <p>page 7, line 19 - page 7, line 34; figure 1</p>	<p>7</p>
Y	<p>EP 0 353 972 A (KENDALL & CO) 7 February 1990 (1990-02-07)</p> <p>column 5, line 39 - column 11, line 10; figures 2-9</p>	<p>8-10,14, 60,62,63</p>
Y	<p>WO 93/22996 A (AVERY DENNISON CORP) 25 November 1993 (1993-11-25)</p> <p>page 9, line 21 - page 13, line 25; figures 2-7</p>	<p>11-13, 15-18, 64-66</p>
Y	<p>US 3 742 951 A (ZAFFARONI A) 3 July 1973 (1973-07-03)</p> <p>column 3, line 42 - column 5, line 26; figures 1,2</p>	<p>36,55</p>
A	<p>EP 0 259 136 A (ALZA CORP) 9 March 1988 (1988-03-09)</p> <p>the whole document</p>	<p>1-36, 38-69</p>
A	<p>EP 0 093 262 A (HYMAN SY) 9 November 1983 (1983-11-09)</p> <p>the whole document</p>	<p>1-36, 38-69</p>
A	<p>WO 93/00115 A (FISCHEL GHODSIAN FARIBA) 7 January 1993 (1993-01-07)</p> <p>the whole document</p>	<p>1-36, 38-69</p>

Patent Family Annex
Information on patent family members

International Application No
PCT/US2004/005602

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9817263	A	30-04-1998	AU 5095698 A WO 9817263 A1	15-05-1998 30-04-1998
WO 0152823	A	26-07-2001	AU 3104301 A WO 0152823 A2 US 6638528 B1 US 2002004065 A1	31-07-2001 26-07-2001 28-10-2003 10-01-2002
WO 9704758	A	13-02-1997	AU 6708996 A AU 6709096 A AU 6709196 A CA 2228034 A1 EP 0840600 A1 GB 2319473 A IE 960539 A1 IE 960540 A1 WO 9704757 A1 WO 9704758 A1 WO 9704759 A1 JP 11510157 T	26-02-1997 26-02-1997 26-02-1997 13-02-1997 13-05-1998 27-05-1998 11-03-1998 11-03-1998 13-02-1997 13-02-1997 13-02-1997 07-09-1999
WO 02067677	A	06-09-2002	WO 02067677 A2 US 2002160035 A1	06-09-2002 31-10-2002
WO 9516754	A	22-06-1995	EP 0734425 A1 JP 9506564 T WO 9516754 A1 US 5589122 A US 5599602 A	02-10-1996 30-06-1997 22-06-1995 31-12-1996 04-02-1997
EP 0353972	A	07-02-1990	AT 100305 T AU 623161 B2 AU 3893889 A CA 1340190 C DE 68912443 D1 DE 68912443 T2 EP 0353972 A1 JP 2167165 A	15-02-1994 07-05-1992 01-02-1990 15-12-1998 03-03-1994 25-08-1994 07-02-1990 27-06-1990
WO 9322996	A	25-11-1993	AU 4104393 A CA 2135611 A1 EP 0665736 A1 JP 7506866 T US 2002147437 A1 US 2002151865 A1 WO 9322996 A1 US 6365793 B1	13-12-1993 25-11-1993 09-08-1995 27-07-1995 10-10-2002 17-10-2002 25-11-1993 02-04-2002
US 3742951	A	03-07-1973	NONE	
EP 0259136	A	09-03-1988	US 4938759 A AT 59968 T CA 1297754 C DE 3767412 D1 EP 0259136 A2 GR 3001328 T3 JP 2511472 B2 JP 63119421 A	03-07-1990 15-02-1991 24-03-1992 21-02-1991 09-03-1988 31-08-1992 26-06-1996 24-05-1988

Patent Family Annex

Information on patent family members

I. International Application No

PCT/US2004/005602

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0093262	A	09-11-1983	US 4285468 A	25-08-1981
			EP 0093262 A1	09-11-1983
			AU 531497 B2	25-08-1983
			AU 4966179 A	13-11-1980
			CA 1133853 A1	19-10-1982
			DE 2967234 D1	31-10-1984
			EP 0019010 A1	26-11-1980

WO 9300115	A	07-01-1993	US 5455043 A	03-10-1995
			WO 9300115 A1	07-01-1993
